SECTION 2

PHARMACY MANUAL

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1 GENERAL POLICY

The Utah Department of Health, Division of Health Care Financing (DHCF) covers most medications prescribed by qualified practitioners as a Medicaid benefit, in compliance with Federal law (42 CFR 440.120). All drugs or products must have an NDC number. [Social Security Act, Section 1927 (K)(3)] Medicaid covers legend drugs with some exceptions and restrictions outlined in Omnibus Budget Reconciliation Act (OBRA) 1990 and 1993 and further identified in this manual, some over-the-counter products, and generic products. This manual is updated by Medicaid Information Bulletins (MIBs) mailed to Medicaid providers. (The Amber Sheet, a publication of the Drug Utilization Review (DUR) Board, is not an official Medicaid publication; it contains general information and educational items.)

1 - 1 Legal References

Utah Public Law SB 114 mandates pharmacists to substitute "A" rated generically equivalent drugs for a prescribed name-brand product when made available by manufacturers. The Division of Health Care Financing requires all pharmacies to dispense generically within the intent and guidelines listed in this law and under the conditions established.

Pharmacy Practice Act: Senate Bill 79 enacted by the Utah legislature in 1996 made changes in pharmacy practice and the functions of technicians.

Controlled Substance Amendment: Senate Bill 281 adds penalties and other items to the Controlled Substances Act.

1 - 2 Federal Upper Limit List

CMS, through the Federal Upper Limit Bureau, provides a biyearly list to the State Medicaid agency which contains the mandated generic, multi-source level of reimbursement for the identified drugs. The Federal Upper Limit List is generally reissued January 1 and July 1. First Data Bank, under contract to Utah Medicaid, maintains these pricing regulations on the Utah Master Reference File. Generic substitution may only be made with products with an A B rating identified in the Approved Drug Products (orange book) published by the U. S. Department of Health and Human Services. The Federal Upper Limit information is available through the Medicaid Point of Sale system and on the Internet at

http://cms.hhs.gov/medicaid/drugs/drug10.asp

A printed copy of the list may be obtained by contacting Medicaid Information.

The reimbursement allowed by CMS is determined by 150% of the average of the lowest three products in the multi-source class. The purchase of all generic products from a single manufacturer may leave some products unavailable at the FUL level. Although a pharmacy may choose not to stock multiple brands and has only products more costly than the FUL, a Medicaid client may NOT be charged the difference between the FUL and the pharmacy cost.

A pharmacy may not dispense a house brand generic product and bill Medicaid for an NDC of a name brand or generic brand product. The name or manufacturer or NDC for the product dispensed must be recorded on the prescription.

Pharmacy Reimbursement
Medicaid currently pays the lesser of Federal Upper Limit (FUL), State MAC, AWP - 15%, or submitted charge. Pharmacies must submit their lowest usual and customary charges to Medicaid, including promotional rates such as $4.00 generics, if they are offered to the general public. Due to pending legal action that resulted in a temporary injunction, the implementation of the AMP-based reimbursement methodology and new AMP-based Federal Upper Limits, as outlined in the Deficit Reduction Act, has been put on hold. No further information is available at this time. Medicaid will continue to publish information as it becomes available.

1 - 3 Utah MAC List

The Division of Health Care Financing (DHCF), Bureau of Coverage and Reimbursement, maintains the Utah Maximum Allowable Cost (MAC). A current list of State MAC prices will be posted on the Medicaid Pharmacy Services Website at http://health.utah.gov/medicaid/pharmacy .

1 - 4 New Products

Any new legend drug product, new size of an existing approved product, or new strength of an existing approved product may be reimbursable, subject to Medicaid limitations and/or prior approval. New drugs will be reviewed for limitations such as prior approval, quantity, and frequency. New drugs may be withheld from coverage for no more than twelve weeks while restrictions or limitations are being evaluated.

New drugs may also be reviewed for off-label or experimental uses. Refer to Chapter 2 - 1, Formulary.

1 - 5 Clients Enrolled in a Managed Care Plan

*A Medicaid recipient enrolled in a managed health care plan (MCP), which includes pharmacy services, must receive all pharmacy services through that plan. A MCP may designate a particular provider as the ONLY provider approved by the MCP to receive payment for services to an enrolled Medicaid recipient.

A provider must be affiliated with the client's managed care plan in order to receive payment for services. Each plan may offer different benefits and restrictions than the Medicaid scope of benefits. The plans which include pharmacy services specify which are covered, which require prior authorization, the process to request authorization and the conditions for authorization. All questions concerning services covered by or payment from a managed care plan must be directed to the appropriate plan.

Reference: Utah Medicaid Provider Manual, SECTION 1, GENERAL INFORMATION: Chapter 4, Managed Care Plans; Chapter 5, Verifying Eligibility - how to verify a patient's Medicaid eligibility and possible enrollment in a managed care plan.

***NOTE:** Since November 1997, none of the Medicaid MCP's have covered pharmacy services. All pharmacy services are fee-for service.

1 - 6 Fee-for-Service Clients

A **fee-for-service** client is a Medicaid client who is either (1) **not** enrolled in a managed care plan or (2) *is enrolled in a managed care plan in which pharmacy benefits are not included ('carved out'). Fee-for-service clients, with the exception of clients in the Restricted Program, may receive pharmacy services from any pharmacy provider who accepts Medicaid.

You should **REQUIRE** the client's proof of eligibility **BEFORE** you provide service and **EACH TIME** you provide service. Proofs of Medicaid eligibility are the Medicaid Identification Card or Interim Verification of Medicaid Eligibility. Proof of eligibility for the Baby Your Baby Program is the Baby Your Baby Card. Look *carefully* at the dates of eligibility on the client's card. If the card is hand-written, you may wish to copy the card to substantiate your Medicaid claim. Medicaid does not pay claims for services after the client's eligibility expires.

The Medicaid Point of Sale system 'captures' a claim even when the computer system has no information as to the client's eligibility. The system returns the message 'claim captured' to advise the pharmacy the claim has been received by Medicaid. The message 'claim captured' does NOT guarantee payment. If the system is subsequently updated, and the claim is within the client's dates of eligibility, it may be paid. If eligibility information is not posted to the Point of Sale system, the claim will be denied. You will NOT receive payment for the services given to the client unless you have a copy of the proof of eligibility the client presented at the time of service which verifies eligibility on the date of service.

Reference: SECTION 1, GENERAL INFORMATION: Chapter 3 - 2, Restricted Program; Chapter 5, Verifying Eligibility - how to verify a patient's eligibility and possible enrollment in a managed care plan.

Client Identification Numbers Ending in 'V' or 'X'

Clients whose number ends in 'V' have a Baby Your Baby Identification Card. Clients whose number ends in 'X' have an Interim Verification of Eligibility (Form 695). You may wish to copy the card or form to substantiate your Medicaid claim. When a temporary proof of eligibility expires, Medicaid will no longer pay claims, unless the client has since been issued a Medicaid Identification Card for the month of service.

Expiration Date on Baby Your Baby Card

A woman eligible for a Baby Your Baby Card is told to present the Card **each time** she requests prenatal services. The card has an **initial expiration date** pending a formal decision of eligibility for Medicaid. If a determination of Medicaid eligibility cannot be made before the initial card expires, the **Medicaid eligibility worker may extend** the expiration date on the card.

Expiration Date on Interim Verification of Medical Eligibility (Form 695)

An "Interim Verification of Medical Eligibility" (Form 695) with date limits may be issued by the Medicaid eligibility worker when a client needs proof of eligibility and does not yet have the Medicaid Card.

1 - 7 Quality Improvement Programs

1. Retrospective Drug Utilization Review (RetroDUR)

The State Drug Utilization Review Board will use Retrospective Drug Utilization Review (RetroDUR) studies to review prescribing and dispensing patterns for Medicaid patients. The Board is comprised of providers nominated by the Utah Medical Association, the Utah Pharmaceutical Association, and the Utah Dental Association.

RetroDUR studies are required by the Omnibus Reconciliation Act (OBRA) of 1990. The University of Utah College of Pharmacy developed the drug criteria sets. Academicians from the School of Medicine and the School of Pharmacy reviewed the sets with the Drug Utilization Review (DUR) Board. Sets approved by the DUR include:

- Antidepressant drugs
- Centrally acting skeletal muscle relaxants
- Gastrointestinal agents
- Nonsteroidal anti-inflammatory agents
- Migraine usage
- Oral asthma / inhalation
- Oral opioids
- Anti-convulsants
- Lipodemics
- Atypical Antipsychotics
- Benzodiazepines
- Bladder anti-spasmodics
- Narcotic pain medications

To order a copy of the drug criteria sets, please contact Medicaid Information.

2. Comprehensive NeuroScience (CNS)

Comprehensive NeuroScience (CNS) has been contracted to evaluate the use of atypical antipsychotics as well as other psychotropic medications in the Medicaid program in an effort to identify inappropriate use, poly-pharmacy, doctor shopping, etc. These evaluations are supported by contact with prescribers through the use of letters and peer-to-peer consultations with acknowledged specialists and experts in the field of psychiatry.

3. Medicaid Transformation Grant

The Transformation Grant for Utah Medicaid involves developing a Utah Pharmacotherapy Risk Management System with an Electronic Surveillance Tool (Utah ePRM). This grant brings together staff from the Utah Division of Health Care Financing, the Utah College of Pharmacy, the School of Medicine, the Department of Pediatrics, the Office of Health Care Statistics, and the Salt Lake VA Medical Center to modernize Utah Medicaid's health delivery system.

The targeted interventions planned for under this grant include:

a) Prescriber notification of potential therapy problems by letters, and in some severe situations, by telephone.
b) Identification of prescriber outliers and use of face-to-face academic detailing.
c) Detection of client fraud and abuse and expanded use of the restriction Lock-In program.
d) Patient reviews for those clients at high risk.
e) Medication Therapy Management Services (MTMS) by certified pharmacists.

Appropriate therapy and safety outcomes will be the overall focus of this program including under use of needed medication. The six areas of focus will include a) diabetic therapy, b) hypertension therapy, c) asthma therapy, d) antipsychotic therapy, e) pain management, and f) anticoagulation therapy.

1 - 8 Co-payment Required for Medicaid Prescriptions

Effective February 1, 2003, most Medicaid recipients are required to pay a $3.00 co-payment for each prescription filled. **The Point of Sale system informs you when a co-payment is due.** When Point of Sale (POS) shows a $3.00 co-payment, the Medicaid recipient is expected to pay the $3.00 in order to receive the prescription. There is a $15.00 monthly maximum on co-payment in the Traditional Medicaid Program.

1. Recipient Notification

Medicaid recipients who are required to pay the co-payment receive a Medicaid Card which states 'Co-payment required for pharmacy'. The July 1997 Medicaid Cards were the first ones with this message. A letter was sent with both the June and July 1997 Medicaid Cards to inform recipients of the new requirement.

2. Exempt Recipients

Some Medicaid recipients are exempt from the pharmacy co-payment, due to age or other specific criteria. Point of Sale will not indicate a co-payment when the recipient is exempt.

A. When any or all of the recipients listed on the Medicaid Card are required to pay the co-payment, the Card will have the 'Co-payment required' message. Because a family eligible for Medicaid may contain adults required to make a co-payment and children who are exempt from the requirement, **you must use Point of Sale** to know whether the patient with a prescription has a co-payment or not.

B. When all of the recipients listed on the Medicaid Card are exempt, the Card will NOT have the message 'Co-payment required for pharmacy'.

For your information, the following groups of Medicaid recipients are exempt from the co-payment requirement:

(1) Recipients enrolled in a MCP that includes prescription drug coverage, with one exception for protease inhibitors as described in paragraph number 5. NOTE: As of November 1997, none of the Medicaid MCP's cover pharmacy services. All pharmacy services are fee-for service.

(2) Children under age 18.

(3) Residents of a nursing home who are entitled to keep only the $45 personal needs allowance.

(4) Pregnant women, as determined by the Medicaid eligibility worker.

(5) Recipients whose monthly household income is less than the payment amount in the Family Employment Program, as determined by the Medicaid eligibility worker.

3. No Copay on Prescriptions for Family Planning

Point of Sale will NOT indicate a co-payment on family planning prescriptions, such as birth control pills.

4. Maximum $15.00 a month Co-payment for Each Recipient In the Traditional Medicaid Plan

Once a recipient has met an individual maximum co-payment of $15.00 a month for his or her prescriptions, Point of Sale will NOT indicate a co-payment is due. Medicaid will keep track of the cumulative number of prescriptions for a recipient with $3.00 co-payments. Once five prescriptions with $3.00 co-payments have been filled, Point of Sale will no longer indicate a $3.00 co-payment. Reversal of a previously filled prescription with a co-pay will require a refund of the co-pay to the individual, and will cause the next prescription filled for that recipient to be adjudicated with a co-pay.

5. Protease Inhibitors

Point of Sale will indicate a co-payment is due for drugs classified as protease inhibitors, even though the recipient's Medicaid Card may not have the message 'Co-payment required for pharmacy'.

6. Recipients with Temporary Proof of Eligibility

When the client has an interim Form 695, Verification of Medicaid Eligibility, and the Point of Sale system (POS) does not yet display Medicaid eligibility information, we ask that you do **NOT** collect a co-payment unless the form is stamped 'Co-payment REQUIRED.' (To ensure reimbursement when a client's number ends with letter 'X', ALWAYS require the client's proof of eligibility.) The Medicaid eligibility worker will add the statement 'Co-payment REQUIRED' to the top of the Form 695 when applicable for the adults listed on the form. A co-payment should **never** be collected when dispensing prescriptions for children who are under age 18.

In addition, we recommend you do **NOT** require a co-payment when the prescription is for family planning, such as birth control pills.

Please note the pharmacist cannot exempt the co-payment on the basis of pregnancy or household income. These exemptions can only be determined by the Medicaid eligibility worker.

Typically, POS receives eligibility information overnight. When the pharmacy claim is entered the day after the initial determination of Medicaid eligibility, the co-payment indicator will state whether $3.00 will be subtracted from the reimbursement amount.

When POS displays eligibility information for the client, **you must use Point of Sale** to determine when to collect a co-payment, regardless of whether the Form 695 has a copay message or not. Once a Medicaid Identification Card has been issued, POS determines when a co-payment is due, even though the client may be using a Form 695 as a substitute for a missing Medicaid Card.

7. Baby Your Baby Program

NEVER collect a co-payment from a client eligible for the Baby Your Baby Program on the date of service. A co-payment will **NOT** be assessed by Medicaid. When a client's number ends with letter 'V', ALWAYS require the Baby Your Baby Card and CHECK THE DATES OF ELIGIBILITY.

QUESTIONS?

When Point of Sale is not available, and you cannot determine whether a co-payment is due or not, you may call Medicaid Information. In the Salt Lake City area, call 538-6155. In other areas of Utah, call toll-free 1-800-662-9651.

If a Medicaid recipient has a question about whether he or she is exempt from the co-payment, the recipient should contact his or her eligibility worker. If the recipient has a question about being charged a co-payment, whether for a certain type of prescription or being charged for more than five prescriptions in a month, he or she should discuss this with the pharmacist. If the recipient continues to have questions or concerns, he or she should talk to the eligibility worker.

1 - 9 Internet Access to Medicaid Manuals

SECTION 2 of this Medicaid Provider Manual is accessible on the Internet. Go to the Medicaid website at http://health.utah.gov/medicaid and choose the link to "manuals". The most recent edition of the manual and attachments can be accessed, as well as the past two years in archives.

1 - 10 Tamper Resistant Prescription Pad Requirements

In May 2007, Congress passed a bill that required that effective October 1, 2007, written prescriptions for drugs under the Medicaid program must be on tamper-resistant prescription pads. The effective date of this bill has now been changed to April 1, 2008.

Effective April 1, 2008, all new written Medicaid prescriptions (except those for residents of nursing facilities, intermediate care facilities for the mentally retarded (ICF/MR), or other specified institutional and clinical settings) must be written on tamper-resistant prescription pads. The following requirements are mandated:

1. Applies only to written prescriptions. Prescriptions that are electronic (those that are faxed, taken over the phone, or transmitted through other electronic means) are not covered under this law.
2. Applies only to new prescriptions filled on or after April 1, 2008. Does not apply to refills of prescriptions initially filled prior to April 1, 2008, until law requires a new prescription.
3. Compliance with all federal and state laws regarding the types of documentation and how prescriptions are filled must be maintained.

If a pharmacy fills a prescription that does not comply with the requirements above, funds paid by Medicaid will be recovered. Prescribers will have to ensure that pads used to write Medicaid prescriptions meet the following requirements in order to be considered "tamper-resistant". If not, the patient will likely be sent back to get another prescription written on a compliant prescription form.

Effective April 1, 2008, the prescription form must contain at least one of the following three characteristics:

1. One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;
2. One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber;
3. One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

Effective October 1, 2008, to be considered tamper-resistant, a prescription pad must contain all three of the above characteristics.

2 COVERAGE OF SERVICES

When a client wants medications not covered by the Medicaid program, the client may choose to pay for the non-covered medications. For information on the circumstances in which a client may be billed for non-covered Medicaid services, refer to the SECTION 1 of this manual, Chapter 6 - 8, Exceptions to Prohibition on Billing Patients, item 1, Non-Covered Services. The on-line version of SECTION 1 is at http://health.utah.gov/medicaid/pdfs/SECTION1.pdf.

2 - 1 Formulary

OBRA 1993, Section 1927 (d) (6) states: "Effective October 1, 1993, states may exclude, restrict, or subject to prior authorization new drugs approved by the Food and Drug Administration (FDA)." However, Utah law prohibits Utah Medicaid from having a closed formulary. Utah Medicaid maintains an "open" formulary with a few drug classes not covered as allowed by OBRA and Utah Law.

During the 2007 legislative session, the Utah State Legislature passed Senate Bill 42 allowing Medicaid to adopt a preferred drug list (PDL). Medicaid's goal is to begin to phase in a preferred drug list beginning fall 2007.

A Pharmacy and Therapeutics (P&T Committee), consisting of an academic pharmacist, a hospital pharmacist, a chain store pharmacist, an independent pharmacist, a government pharmacist, a pediatrician, a family practice physician, a psychiatrist, and an internist, will advise the DUR Board and Medicaid in choosing preferred agent(s) for each selected class of drugs based on clinical efficacy and cost.

Continual public updates about the PDL implementation process will be provided through the Amber Sheet, MIB, and Pharmacy Services web site at http://health.utah.gov/medicaid/pharmacy .

Once the PDL becomes effective:

If a prescriber wishes to prescribe a non-preferred drug, he or she will need to write the words "*Dispense As Written - Medically Necessary*" on the prescription and document the reason in the patient's medical record in order for Medicaid to cover the drug.

Pharmacies that receive prescriptions for non-preferred agents with the words "*Dispense As Written - Medically Necessary*" written on the prescription will need to put a DAW code of "1" and a submission clarification code of "7" on the claim in order for it to be covered.

2 - 2 Prescribed Legend Drugs

A. Prescribed legend drugs are covered with the following limitations:
   1. Non-covered drugs which are listed in Chapter 2-3, Non-covered Drugs and Services.
   2. Drugs which require prior approval.
   3. Drugs by manufacturers who have not entered into a rebate agreement with CMS.
   4. Nutritional substances.
   5. Metabolic nutritional products.

B. Off-Label, Experimental and Investigational Drugs

   The Utah Medicaid Program restricts the covered drug products on the open formulary to uses approved and documented by the officially recognized compendia [OBRA 1993, section 1927 (d) (6)]. The designated compendia are:
   1. Package insert, FDA approved uses
   2. American Hospital Formulary Service Drug Information (AHFS)
   3. American Medical Association Drug Evaluation (AMADE)
   4. United States Pharmacopeia Drug Information Drug Information (USP- DI)
   5. DRUGDEX

Off-label Use

The Drug Utilization Review (DUR) Board may approve, for a specific case, an unlisted off-labeled use for a given drug if the off labeled use meets ALL of the following criteria.

1. Use must be diagnosis specific as defined by an ICD-9 code (s).

2. Off-labeled use must be supported by one major multi-site study or three smaller studies published in JAMA, NEJM, Lancet or peer review specialty medical journals such as Journal of Cardiology. Articles must have been published within five years.

3. Off-labeled use must have a defined dosage regimen.

4. Off-labeled use must have a defined duration of treatment.

5. The off-labeled use shows clear and significant clinical or economic advantage over existing approved drug regimens.

Experimental Use

Experimental use is defined as drug use for indications not supported by FDA or published studies. Drugs prescribed for experimental use are **not** covered. Experimental drugs or herbal products are not covered. As documentation accumulates for a given indication, the experimental drug use may move to the off-label category or be approved as a labeled indication, as determined by the DUR Board.

Investigational Use

Investigational drugs or chemicals are not covered. Any drug or chemical that does not have an NDC number is deemed investigational.

The UMA, Utah based Group Practices or Utah based prescribers have the option of petitioning the DUR Board for coverage for an unlisted, off-labeled use of a given drug. The petitioner(s) must schedule an appearance before the Board to present the case for the petitioned drug. Petitioners must provide documentation including one published major multi-cite study or a minimum of three recent (five years) articles from JAMA, NEJM, Lancet or peer review specialty medical journals such as the Journal of Cardiology, supporting the petition's position. If possible, the documentation must be submitted two weeks in advance of the scheduled DUR Meeting.

2 - 3 Non-covered Drugs and Services

Only drugs and services described previously as covered are reimbursable by Medicaid. This chapter summarizes those products and services which are not covered.

OBRA 1990, Section 1575 (d) (2) states: "The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted by a state participating in the master rebate agreement."

1. Agents when used for anorexia, weight loss or weight gain.

2. Agents when used to promote fertility.

3. Agents when used for cosmetic purposes or hair growth.

4. Agents when used to promote smoking cessation. However, because Utah participates in the Tobacco Settlement, coverage is being provided for cessation products until these funds expire, at which time coverage will then no longer be available.

5. Vitamins, except when provided for:
   - Pregnant women: prenatal vitamins with folic acid (prenatal vitamins are not covered post-delivery)
   - Children through age five: children's vitamin drops with or without fluoride
   - Adults and children of all ages: fluoride supplement

6. Nonprescription drugs. However, Utah has chosen to pay for a limited list of OTC drugs.

7. Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests and monitoring services are purchased exclusively from the manufacturer or its designee.

OBRA 90 also includes barbiturates, benzodiazepines, and cough and cold preparations. Utah Medicaid has chosen to include barbiturates and benzodiazepines, and a limited selection of cough and cold products. Utah has also chosen to exclude coverage of drugs available only through unique, single-source distribution programs.

Beginning July 1, 2007, only the following legend cough and cold preparations will be available for coverage through the Medicaid program:

Legend cough and cold agents used for symptomatic relief:
Guaifenesin with DextroMethorphan (DM) 600/30 tab
Guaifenesin with Hydrocodone 100/5 liquid
Promethazine with Codeine
Histinex HC (generic equivalents only)
Rondec and Rondec DM (generic equivalents only)

Covered over-the-counter cough and cold remedies are given in the approved OTC list.

In addition, the following are not covered benefits:

A. Any drug without a prescription, including over-the-counter drugs, is not a benefit.

B. Any drug or product for which an NDC number is not available is not a Medicaid benefit. [Social Security Act, Section 1927 (K)(3)]

C. Over-the-counter drugs not on the approved Over-the-counter Drug list are not a Medicaid benefit.

D. Certain OTC drugs on the approved list are not a benefit for a Medicaid client who is a resident of a nursing home. When this restriction on a drug is indicated, all dosage forms apply.

E. Early refills of prescriptions are not a Medicaid benefit except as specified in Chapter 4 - 7, Early Refills.

F. Drug classes not covered as allowed by OBRA and Utah Law are not a Medicaid benefit.

G. Off-Label Drug Use is not a Medicaid benefit.
Only uses approved as described in Chapter 2 - 2, Prescribed Legend Drugs, item B, are covered by Medicaid.

H. Less-Than-Effective (DESI) Drugs are not a Medicaid benefit.

As stated in Chapter 5 - 4, Desi Drugs, drugs are classified into five groups. Drugs in groups 4, 5, and 6 are NOT covered by Medicaid. DESI drugs are combinations of products and single products that, in the Federal Drug Efficacy Study Information (DESI), have not been proven to CMS to be effective for the conditions indicated in the information packet.

I. Drugs given by a hospital to a patient at discharge (take-home drugs) are not a Medicaid benefit.

J. Breast milk substitutes are not a Medicaid benefit.

K. Multiple vitamins (except for prenatal vitamins with folic acid for pregnant women, and multiple vitamins with or without fluoride for children through age 5) are not a Medicaid benefit.

L. Baby food is not a Medicaid benefit.

M. New pharmaceutical products on the market are often covered by the Medicaid Physician Program and not covered by the Pharmacy Program. The following products are examples: Remicade, Zemplar, TRELSTAR®.

Also, some products removed from coverage by the Pharmacy Program continue to be available through the Physician Program.

N. Prescriptions for medication for erectile dysfunction are no longer covered as of January 1, 2006, due to Federal Law changes.

2 - 4 Prescribed Over-the-Counter Products

Over-the-Counter drugs (OTC) are covered ONLY when (1) the drug is listed on the Medicaid-approved OTC List and (2) the drug is ordered on a prescription. **The OTC list is included with this manual.** See ATTACHMENTS.
OTC drugs are identified in OBRA 1990 as a category that a state may choose not to cover. Utah has chosen to include as a benefit a limited list of over-the-counter products. This list is reviewed twice a year for changes, additions, or deletions. Changes to the list are published in the Medicaid Information Bulletin.

Only the Over-the-Counter drugs on the latest list published in the Medicaid Information Bulletin (MIB) are reimbursable. No other formulas or similar products are a benefit.

1. OTC drugs NOT on the approved list are NOT covered.
2. Certain OTC drugs on the approved list are not a benefit for a Medicaid client who is a resident of a nursing home. When this restriction on a drug is indicated, all dosage forms apply.
3. Limits and criteria may also be noted on the OTC list after the drug name.
4. Excessive utilization or waste may cause the whole class to be dropped from the program.
5. OTC drugs are not covered for manufacturers who have not entered into a rebate agreement with CMS.

2 - 5 Generic Preparations

Medicaid requires use of generic drugs, unless the physician obtains a prior approval for the brand name drug. However, Medicaid does not pay for generic house-brand or store brand products unless the manufacturer has entered into a rebate agreement for each specific NDC number. Manufacturers that have not entered the federal rebate program will not have their products covered. This includes almost all ‘house brand’ and ‘store brand’ products.

In a very few limited instances, manufacturer rebates can create situations where the brand name version of a drug may cost less. These situations are rare and will be investigated by the pharmacy program managers. When substantiated, Medicaid may reimburse for that brand product as a cost saving measure after evaluation reveals that the savings will be maintained for the program. These exceptions will be subject to strict requirements on the part of manufacturers. Coverage extended will undergo continuous re-evaluation, and notice will be provided if and when these instances occur.

3 PRIOR APPROVAL

Prior Authorization (PA) confirms that services requested are needed and reimbursable by Medicaid, that they conform to commonly accepted medical standards, and that all less costly or more conservative alternative treatments have been considered.

Prior authorization falls into two categories.

1. Services or drugs beyond the designated limitations

2. Services or drugs specifically identified as requiring prior authorization

The physician requests the prior authorization in accordance with the requirements stated on the Drug Criteria and Limits List. If any exception is noted, Medicaid requires the physician to obtain prior authorization in writing or by telephone in advance of the date of service. Nothing in this chapter would preclude a pharmacy from deciding to act as intermediary for the request, should they choose to do so. Products which require prior approval are on the Drug Criteria and Limits List with a description of the type of approval required and the criteria. The list may be amended by Medicaid Information Bulletins.

Prior authorization for a pharmaceutical is client specific, pharmacy specific, and product specific.
Prior authorization cannot be transferred to another pharmacy, to another product, to another strength of a previously authorized product, nor to another client. Refer to Chapter 3 - 2. Prior Authorization Is Provider Specific.

3 - 1 Fee-for-Service Clients

Prior authorization requirements for pharmacy services apply to ALL fee-for-service clients, defined in Chapter 1 - 6, even though the client may be enrolled in a managed care plan which provides other types of health care services.

The PA requirements and process do **not** apply to Medicaid patients enrolled in managed care plans which include pharmacy services. Those plans specify which services require authorization and the conditions for authorization.

NOTE: Medicaid staff make every effort to ensure information provided is accurate. However, obtaining a prior authorization number does not ensure that the client is eligible for Medicaid on the date of service, and neither does it ensure that the client is not enrolled in a managed care plan which includes pharmacy services.

3 - 2 Prior Authorization Is Provider Specific

When a prior authorization is issued, the prior authorization number includes the pharmacy's Medicaid Provider Identification Number. The authorization number is valid only for the pharmacy provider filling the prescription. It is not transferrable to another pharmacy provider, including another store in the same chain. For example, prior authorization given to ABC Pharmacy #00 for John Doe for growth hormone cannot be used by XYZ Pharmacy nor by ABC Pharmacy #99.

Claims submitted for refills which require prior authorization can be paid only when the prior authorization number for the drug matches the provider number on the claim. Claims will be denied when the prior authorization number does not match the provider number. Claims submitted through the Medicaid Point of Sale payment system which deny for this error reason will state: "Claim submitted does not match prior authorization."

If the prescription is transferred to a different pharmacy, the existing prior approval (PA) must be terminated. The new pharmacy can then request its own PA for the remaining doses. The new pharmacy must obtain all information and documentation required for the PA. It may either obtain this from the pharmacy with the original PA or from the prescriber. Medicaid will assign a new PA number with the original end date for the residual doses. The second pharmacy cannot start the prescription with a new number of doses or a new time span.

3 - 3 Prior Authorization Process

1. A physician may request prior approval by telephone supplying identified information specified on the Drug Criteria and Limits List, or the physician may initiate and complete a written request for Prior Approval when necessary. The prescriber furnishes information to justify the need and may submit it either by mail or by Fax. Request for renewing a prior approval must contain justification, along with any additional information required. Do not refer only to the previous prior approval number.

   a. Written Prior Authorization

      Mail written requests to:

      MEDICAID PRIOR AUTHORIZATION
      P.O. BOX 143103
      SALT LAKE CITY UT 84114-3103

   b. Fax Number

      Prior authorization requests may be faxed to **(1-801) 538-0477**, attention "Prior Authorizations"

   c. Telephone Prior Authorization

      Call Medicaid Information, then follow the telephone menu prompts.

      In the Salt Lake City area, call **538-6155**

      Call toll-free in Utah, Arizona, New Mexico, Nevada, Idaho, Wyoming and Colorado **1-800-662-9651**

      From all other areas **1-801-538-6155**

2. If documentation is complete and the request is approved, Medicaid notifies the provider of the prior authorization number. The provider supplies the services to the recipient and bills the Department of Health, Division of Health Care Financing, through the Point of Sale adjudication system identifying the prior approval number.

3. If documentation is incomplete, the prior approval specialist outlines documents or actions necessary to approve the request for telephone or written prior approval.

4. If the prior approval request is denied, a letter of denial with an explanation is returned to the requestor, and a copy of the denial and explanation is sent to the recipient.

   Any further questioning by provider must be referred to the prior approval specialist who is responsible for the initial action. The signature on the denial or the signature on the letter of information will identify the specialist.

4 COVERAGE LIMITATIONS

Medicaid coverage of pharmaceuticals is subject to the limitations described in this chapter. When the drug requires prior approval, it is included on the drug criteria chart with any age restriction indicated.

4 - 1 Gender and Age of Patient

Drugs must be for the correct gender and/or appropriate age. Examples of gender specific drugs are as follows:

Drug type	Gender
Prenatal	Female
Oral contraceptives	Female
Estroderm	Female

Age limitations on drugs are announced in the Medicaid Information Bulletin. Examples of age restrictions are multiple vitamins, a Medicaid benefit only for children through age five; Multiple vitamin supplement (vitamins A, C, and D) without fluoride covered for children up to five years of age only; acne preparations, only for children through the month of the twenty-first birthday.

4 - 2 Maintenance Drugs

Definition: A maintenance medication is any medication or covered pharmacy supply used on an ongoing basis.

Medicaid does not cover any payments for dispensing medications in excess of the practitioner's order. If special circumstances warrant, the pharmacist must provide written documentation on the prescription which must be available for review by the Division of Health Care Financing.

The pharmacist will receive payment for maintenance medications on the basis of one and only one professional fee for:

1. each 30 or 31 days supply of tablets, capsules, bulk liquids, or topicals: or

2. manufacturers' prepackaged powders, topicals, ophthalmic, optics, nasal preparations, and liquids not available in bulk.

3. a trial quantity of less than 30 or 31 days' supply;

4. glucose test strips. Refer to Chapter 5, Special Drug Provisions, item G.

4 - 3 Controlled Substances

Controlled drugs in Schedule II, which are highly regulated and specifically and totally controlled, must be dispensed as written, and will be reimbursed on that basis for all Medicaid clients.

Schedule medications (C - III, IV, or V) are not classified as maintenance medications for reimbursement purposes although they may otherwise fulfill maintenance medication criteria. Physicians may prescribe a 30 day supply.

Schedule II and III controlled substance analgesics, and Schedule II long acting analgesics have specific limits as described in the Drug Criteria and Limits List included with this manual (see also Chapter 4-9, Limits on certain drugs).

4 - 4 Prior Approval Policy for Name Brand Drugs

Brand name drugs require a prior approval (see chapter 3) if an 'AB' rated generic alternative is available. The Utah Pharmacy Practice Act mandates use of a generic unless the treating physician demonstrates to the Department of Health a medical necessity for dispensing the non-generic, brand-name legend drug. Prior approval can be obtained by faxing a copy of the information from the patient's medical record that documents that the patient **has had** an unacceptable adverse drug reaction to the generic version that **does not occur** with the name brand or **has failed** to achieve therapeutic efficacy with the generic version. [42 Code of Federal Regulations § 447.331(C) and § 447.331(C)(3)]**. If the prescription does not meet coverage requirements, brand name reimbursement is not covered**, and Medicaid will retract the entire payment. Telephone orders are not acceptable for brand name drugs unless the pharmacist has received the faxed documentation ruling out use of a generic. The pharmacist can then forward that FAX to the Medicaid prior approval unit. Pharmacists will still have to activate the DAW override loop to get full reimbursement on a brand name once a prior approval has been obtained. DAW is not available in the Non-Traditional Medicaid (NTM) program or the Primary Care Network (PCN) program.

Patient preference does not constitute a medical necessity.

If the brand name is not covered, and the client chooses the brand name drug, the client is responsible for the entire payment. For example, Valium® is not covered by Medicaid because the manufacturer does not participate in the rebate program. If the prescription is for Valium®, and the client chooses Valium over the generic product, the client must pay the entire cost.

4 - 5 Drugs for Nursing Home Patients

With the exception of Schedule II drugs, all medications should be dispensed to nursing home clients with a 30 or 31 days' supply.

1. Take Home Drugs

   Medicaid reimburses the pharmacy for a 30 or 31 days' supply of drugs for nursing home patients. If a patient is leaving the facility for therapeutic or social reasons, the dispensing pharmacist must provide a labeled take-home container and must place in the container the specific number of units required for the patient while away from the nursing home. These units are to be taken from the month's supply already provided. No additional units beyond the 30 or 31 days' supply will be reimbursed.

2. Cycle Filled Prescriptions

   Cycle filling of prescriptions is NOT acceptable to Utah Medicaid. A prescription may not be refilled until a minimum of 80 percent of the previous prescription has been used. Refer to Chapter 4 - 7, Early Refills.

   The term "cycle" means some action or procedure performed on a routine basis. For example, 'cycle filled' prescriptions are those filled on a set schedule, usually every 30 or 31 days, with no reference to the use of the previously dispensed prescription. Typically, the routine is to dispense a month's supply of medication for the patient under the physician's orders. At the end of the "cycle," the local or mail order pharmacy delivers to the nursing home or patient's home a new 30 or 31 days' supply of all prescriptions without adjustment for unused units.

   Prescriptions furnished to patients residing in extended care facilities (nursing home) MAY NOT be refilled until the previous prescriptions are used, even when an extended period of time occurs. For example, Darvocet is dispensed generically in a quantity of 60, to be taken two daily. If the patient does not actually take the medication as indicated for 45 or 50 days, the prescription may NOT be reordered or refilled.

   Unique dispensing methods such as tray changes every two days or every seven days do not justify additional fees. One fee per month is reimbursable even when the product is delivered to a nursing home one tablet at a time.

4 - 6 Compounded Prescriptions

Compounded prescriptions are usually an arrangement between a physician and a specific pharmacy to provide a privately designated combination of drugs as a specific entity. Pharmacists sometimes call compounded prescriptions 'simple dilutions' or simple combinations of two already available ointments. These physician and pharmacy arrangements are not in question.

Claims for compounded prescriptions can be accepted for multiple ingredients. Each ingredient and the appropriate quantity for each must be billed under one prescription number or claim. Up to three dispensing fees will be allowed per compounded prescription. (If the prescription only requires two covered ingredients, only two dispensing fees will be paid. Usual fees are $3.90 for pharmacies in urban areas, $4.40 for pharmacies in rural areas, and $1.00 for a covered over the counter product.) While multiple ingredients will receive multiple fees, single ingredient compounds with non-covered diluents or bases will receive one fee despite the difficulty of some compounded entities. Valid NDC numbers for covered drugs are required for fee payment.

Medicaid will reimburse only for the measured quantity of the covered drugs dispensed, plus the calculated dispensing fees per claim. Incorrect quantities will invalidate the claim. All ingredients must be submitted with the claim, including those that are not covered. The patient will be charged one co-pay for each covered NDC in the compound up to the maximum allowed of five (5). **When submitting a compound claim, you are required to submit the following fields for a paid claim:**

"Compound Dosage Form Description Code" (field ID #450-EF), which indicates the form the compound will be in its final form. Values are as follows:

01=Capsule	02=Ointment	03=Cream	04=Suppository
05=Powder	06=Emulsion	07=Liquid	10=Tablet
11=Solution	12=Suspension	13=Lotion	14=Shampoo
15=Elixer	16=Syrup	17=Lozenge	18=Enema

"Compound Dispensing Unit Form Indicator" (field ID #451-EG), which indicates how the final product will be measured. Values are as follows: 01=Each 02=Grams 03=Milliliters

"Compound Route of Administration" (field ID #452-EH) indicates how the final product will be used by the client. Values are as follows:

01=Buccal	02=Dental	03=Inhalation	04=Injection
05=Intraperitoneal	06=Irrigation	07=Mouth/Throat	08=Mucous
09=Nasal	10=Ophthalmic	11=Oral	12=Other/Miscellaneous
13=Otic	14=Perfusion	15=Rectal	16=Sublingual
17=Topical	18=Transdermal	19=Translingual	20=Urethral
21=Vaginal	22=Enteral		

These fields are located in the compound segment. If you are not familiar with where these fields are located, the field ID numbers have been provided for you to discuss with your help desk or software vendor.

*****When you submit a compound claim with non-covered ingredients, you will receive a denial. To process the claim for covered ingredients only, submit the value (8 = Process compound for approved ingredients) in the "Submission Clarification Field", for reimbursement.**

Following are three examples of reimbursement under the compounded policy:

1. A compounded prescription calls for 10 tablets (with an NDC number) to be crushed and placed in a liquid which is NOT a covered item. Submit a single claim for the tablets with the NDC number, plus your usual fee. Medicaid will reimburse for the tablets and one dispensing fee.

2. A compounded prescription calls for 10 tablets (with an NDC number) to be combined in a liquid which also has an NDC number. Submit one claim, for both NDC's. Medicaid will reimburse for the tablets and for the liquid, plus two dispensing fees.

3. The prescription to the right illustrates a compounded prescription. The pharmacist should submit one claim. Bill Decadron, 60 ml, Benadryl Elix, 60 ml, and simple syrup 60ml which is not covered by Medicaid. Medicaid will reimburse for the two legend drugs, plus the total dispensing fee.

Jane Doe 10 State Street	June 9, 1994
Decadron	60 cc
Benadryl Elix	60 cc
Simple syrup	60 cc
Sig: 1 teaspoonful q.i.d.	Signature: J.Doe, MD

4 - 7 Early Refills

Medicaid provides up to a 30 or 31 days' supply of a medication to Medicaid clients each month. Once that has been done, the Division's responsibility has ended. Medicaid pays for a prescription refill ONLY WHEN 80% of the drug is used in accordance with the physician's orders on the prescription and on the label of the medication. For example, a prescription for a 30 or 31 days' supply has been 80% used by the 24th day after it was dispensed and it may be refilled at that time.

A. Early Refills Not Authorized

Medicaid will not pay for a prescription refill under any of the circumstances listed below. Any attempt to refill a prescription through the Point-of-Sale system under these circumstances will be automatically denied.

1. 80% of the drug, in accordance with the physician's orders on the prescription and on the label of the medication, has not been used. For example, a prescription for a 30 or 31 days' supply has not been 80% used until the 24th day after it was dispensed.

2. Medicaid will not pay for a prescription refill when the client does not like the generic version of the prescription, even though the physician writes a new prescription for the name brand. The client may choose to pay for the name brand units or use the generic until the 80% usage or the 24th day is exhausted.

3. Medicaid will not pay for a prescription refill because the client will be out of town for an extended period of time (so-called 'vacation refill.')

4. Medicaid will not authorize an early refill for medications used for palliative treatment or when gross negligence has been displayed by the client.

5. Medicaid will not authorize an early refill for drugs limited by quantity for any 30-day period. Refer to Chapter 4 - 9, Limits on Certain Drugs, and to the Drug Criteria and Limits list included with this manual.

4 - 8 Replacement

Medicaid does not pay for replacement of prescriptions which are lost, stolen or otherwise destroyed. Patches that are destroyed during use or fall off will not be replaced by Medicaid. Replacement of prescriptions is the client's responsibility. The early refill policy described in Chapter 4 - 7, Early Refills, does not allow replacement, even though the physician may write a second prescription to cover the loss. A request may be made to allow the early refill, but only in cases of lifesaving necessity.

4 - 9 Limits on Certain Drugs

Drugs identified on the Drug Criteria and Limits List included with this manual are limited by quantity for any 30-day period. These drugs have a cumulative limit and do not qualify for early refills under Chapter 4 - 7, Early Refills. The limits are those approved by the Drug Utilization Review (DUR) Board. Physicians and other prescribers who feel that a patient has specific needs which exceed the limits may appeal to the DUR Board. All medications remain subject to all other requirements of the Utah Medicaid Pharmacy Program, as described in the Utah Medicaid Provider Manual for Pharmacy Services.

4 - 10 Restriction on Package Size or Description

Medicaid reserves the right to restrict coverage on certain package sizes or package descriptions. For example, Medicaid may choose to pay for a drug in a MDV (multidose vial) and deny coverage of the same drug packaged in ampules.

4 - 11 Multiple Dispensing Fees Associated with Home Infusion Pharmacy Services

The U.S. Department of Justice (DOJ), as part of a legal process, established a "true AWP" for 437 NDC specific products in 2001. The "true AWP" is close to actual acquisition costs. As a result of the directive from the U.S. Department of Justice (DOJ), effective August 1, 2001, the Division of Health Care Financing has established multiple dispensing fees associated with select home infusion pharmacy services. To implement this change in dispensing fees, the Division established an Infusion Committee with representatives of the home I.V. infusion specialty pharmacies. The group placed each of the 437 NDCs in one of five categories, according to difficulty of preparation and overhead costs.

Categories range from one through five. Category one is for services deemed to be the same as those prescriptions normally filled at a typical retail pharmacy. Category five is the most difficult and expensive to prepare.

- Category two includes nebulizer preparations, growth hormone, etc.
- Category three includes simple I.V. antibiotics, anticoagulant treatments, I.V. gamma globulin, etc.
- Category four includes complex antibiotics that require laboratory monitoring and reporting.
- Category five includes chemotherapy I.V.s, pain management, and cardiac ionotropics. For example, chemotherapy requires a separate vertical hood and complete gowning to meet OSHA standards, which adds considerable expense of time and set-up costs.

Categories two through five will have a new dispensing fee effective August 1, 2001.

Category 2	$ 8.90
Category 3	$ 18.90
Category 4	$ 22.90
Category 5	$ 33.90

The NDCs identified by the DOJ then and in the future will be linked to their counterparts for other manufacturers. Other brands will be reimbursed at the same rate as the DOJ's NDCs. All pharmacies will be reimbursed at the same rate for these NDCs.

5 SPECIAL DRUG PROVISIONS

This section contains information for pharmacies concerning particular drugs or drug classes. Information about limits or Prior Authorization criteria for **specific drugs** can be found in the Drug Criteria and Limits attachment included with this manual.

5 - 1 HIV/AIDS Drugs (Protease Inhibitors)

Antiviral therapy, viral blood testing and protease inhibitor provisions are accepted Medicaid treatment for HIV/AIDS patients. All retro viral drugs are reimbursable and protease inhibitors, available in the marketplace through regular channels, are also reimbursable. No prior approval is required.

5 - 2 H Pylori Treatments

Many ulcers are due to infection with the Helicobacter pylori organism. This infection may be eradicated with a short term treatment composed of Metronidazole, tetracycline hydrochloride and bismith subsalicylate. Other combinations with different antibacterials such as Biaxin are also used. New combinations are appearing daily. The treatment is Medicaid approved, but continued use of anti-ulcer medication after the treatment regimen is completed is usually unnecessary.

5 - 3 DESI Drugs

DESI drugs are combinations of products and single products that, in the Federal Drug Efficacy Study Information (DESI), have not been proven to CMS to be effective for the conditions indicated on the label or in the information packet. DESI drugs are not reimbursable.

DESI drugs are classified by CMS and the manufacturers of combination products into five groups numerically identified beginning with Group 2. The groups are:

Group 2 Drugs for which Medicaid will receive federal matching funds for the drug program and the indications for product use have been proven effective.

Group 3 Drugs classified as largely effective for indicated uses and for which federal matching funds are available.

Group 4 Drugs classified as possibly effective for indicated uses and for which federal matching funds are occasionally (perhaps) available.

Group 5 Drugs classified as not effective for indicated uses and for which federal matching funds are not available.

Group 6 New drugs not classified and for which federal matching funds are not available.

Utah Medicaid reimburses drugs in Groups 2 and 3 only. The DESI classification for each product is on the Point of sale System. Drugs in groups 4, 5, and 6 are considered DESI drugs and are NOT covered by Medicaid. A list of DESI drugs is available from the Medicaid Pharmacy Unit.

5 - 4 Enteral and Parenteral Nutrition and Food Supplements

Enteral nutrition is provided to Medicaid patients by a nasogastric, jejunostomy or gastrostomy tube into the stomach or intestines to supply total nutrition when a non-functioning part of the gastro intestinal tract is present.

Parenteral nutrition is total nutrition administered by intravenous, subcutaneous, or mucosal infusion.

Enteral and parenteral nutrition are reimbursable to pharmacies ONLY through the medical supplies program using five digit codes and billing in the CMS 1500 format, electronically or on a paper claim. Refer to the Utah Medicaid Provider Manual for Medical Suppliers.

Some nutrients may have an NDC and remain non-reimbursable in the Pharmacy Program.

Clients requiring total nutrition through surgically attached tubes or semi-permanent nasogastric tubes may have liquid nutritional products that are reimbursable through the Medical Supplies Program.

Clients under the age of five (5) years receiving limited supplementation through the WIC program, may qualify for coverage of supplementation needs above that which WIC provides.

Certain metabolic supplements designed to support in-born errors of metabolism (such as PKU) may be covered, and are billed with an NDC through the point-of-sale system. All supplement coverage requires prior authorization.

5 - 5 Anti-Ulcer Drugs

Over-the-counter (OTC) forms of anti-ulcer drugs are covered. These can be written on any prescription pad or phoned in. The physician must write for the largest package sizes, either stating the amount or simply writing "largest package size" on the prescription. No other units of OTC anti-ulcer drugs will be accepted.

5 - 6 Glucose Monitors with Test Strips

Glucose monitors are available to Medicaid clients with no charge to Medicaid. The Monitor Accu-Check® is provided from the manufacturer to Medicaid clients at no charge. The pharmacists must work with the manufacturer for replacement or reimbursement of monitors. Medicaid need not be contacted

The Accu-Check test strips and all other test strips are Medicaid benefits for the number of tests identified by the physician. Medicaid reimburses pharmacists AWP plus fee - no percentage deduction.

5 - 7 I. V. Therapy

The purpose of I.V. therapy is to sustain life, reduce or eliminate infections, replace or provide necessary chemicals to maintain electrolyte balance, and provide blood products or chemotherapeutics. I.V. therapy and treatment are only used when the Medicaid client cannot use oral medications. I.V. drugs are available through the Traditional Pharmacy Program. Supplies are billed through the Medical Supplies Program. Home health nursing is available through the Home Health Program.

Care must be taken when requesting reimbursement for I.V. products. Liquid injectables (before and excluding diluents) are billed as milliliters. Dry powder, by lyophilized vials, are billed as "each," or a unit of one. Diluents covered by Medicaid are billed separately by NDC and quantity such as 50 ml., 100 ml., 1000 ml.

Recent Federal rulings have disqualified Heparin flushes for coverage under the Medicaid pharmacy program. Any product used to "flush" or maintain an IV line is not considered a pharmaceutical and is not covered.

5 - 8 Niche Drugs

Products mailed directly to a patient from the manufacturer using a single designated distributor are not covered by Medicaid. Manufacturers are increasingly shipping products, developed to target specific diseases, directly to patients via a Pharmacy Benefit Management service.

Medicaid will not enter into agreements or utilize distribution programs that violate patient confidentially or prohibit free trade of a product. When products are available through usual and customary channels to all pharmacies, the products will become Medicaid benefits.

5 - 9 Blood Factors

Medicaid restricts hemophilia blood factors to a single provider. The purpose is to provide a uniform hemophilia case management support program to the patient and patient's physician and to achieve economies in the purchase of blood factor through a sole source contract. Medicaid will reimburse only the sole source provider for hemophilia case management, blood factors VII, VIII and IX. No other provider will be paid for blood factors VII, VIII or IX. Medicaid clients who choose not to participate in the Medicaid Hemophilia program must make their own arrangements for procurement and payment of the blood factor.

The contract affects only the procurement and management of the prescribed blood factor. The patient's physician continues to be responsible to develop a plan of care and to prescribe the blood factor. The contract with the sole source provider specifies the provider must work closely with the patient's Primary Care Provider physician or managed care plan.

Managed care plans which contract with Medicaid continue to be responsible for hemophilia-related services such as physical therapy, lab work, unrelated nursing care, and physician services.

As of October 2000, the sole source provider is University Hospital Home Infusion Services. Please direct questions concerning hemophilia case management and blood factors VII, VIII and IX to this provider: (801) 213-9600.

5 - 10 Immunization Reimbursement Methodology

Medicaid utilizes Centers for Disease Control (CDC) pricing information and Estimated Acquisition Cost (EAC), which is calculated as AWP - 15%, in determining the reimbursement rates for immunizations paid by fee-for-service Medicaid. Medicaid will continue to use lesser logic and reimburse the lower of CDC and EAC.

CDC pricing information can be found at http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm .

6 REIMBURSEMENT POLICIES

6 - 1 Point-of-Sale System

Effective April 1, 2000, Medicaid requires all pharmacy claims to be submitted electronically through the Point of Sale system. Medicaid will only accept a claim submitted on paper when (1) a client becomes eligible for Medicaid after receiving services (retroactive Medicaid) AND (2) the provider's software cannot support a claim with a previous date of service.

Beginning April 1, 2000, Medicaid will return all Universal Pharmacy Claims (NCPDP) submitted on a paper form to the provider with a cover letter requiring the claim be submitted electronically.

Point of Sale System

The Point of Sale (POS) system provides pharmacists with the capability to submit pharmacy claims electronically. It enables pharmacies to immediately determine Medicaid client eligibility, verify drug coverage, and have "real time" claim processing. Federal law has mandated the use of NCPDP 5.1 effective October 17, 2003. NCPDP5.1 is the national claim format developed by the National Council for prescription drugs. All pharmacies routinely billing Utah Medicaid must use NCPDP 5.1 when billing Medicaid through Point-of-Sale.

Pharmacy claims are routed electronically through network companies (switches). The network companies currently participating in this process are National Data Corporation (NDC) and Envoy Corporation. Other interested and qualified networks may also participate.

For information about submitting claims through NDC or Envoy Corporation, please call NDC Easy claim Customer Support at 1-800-388-2316 or Envoy at 1-800-333-6869.

Included with this manual are instructions, and an Resolution List to assist in resolving denials.

6 - 2 Prospective Drug Utilization Review (PRODUR)

PRODUR, Prospective Drug Utilization Review Program, is an adjunct to the Point Of Sale (POS) system used for pharmacy claims. It is a system to monitor the client's complete Medicaid drug history, including any pharmacy or physician. It identifies on the computer screen, as the prescription is being filled, any potential adverse drug events (ADE) of severity level 1, drug duplicates as well as therapeutic class drug duplicates. PRODUR contains modules to review drug interactions and responds with a message to the pharmacist. Modules include: Minimum - Maximum Dose, Dose range (cumulative dose), Duplication, Drug - Drug Interaction, Drug - Disease Interaction, Minimum/Maximum Pediatric Daily Dose, Minimum/Maximum Geriatric Daily Dose and Side Effects Module. (Criteria for the Side Effects Module are listed in this chapter)

If you would like more information on PRODUR, please contact Medicaid Information.

Criteria for Side Effects Module

For the Side Effects Module, First DataBank© has established the following editorial criteria:

a. **Frequency:** A side effect is defined as 'common or more frequent' when the incidence is greater than or equal to 10%. A side effect is defined as 'rare or less frequent' when the incidence is less than 10%.

b. **Severity:** A side effect is defined as 'less severe' if it is nonthreatening (e.g., constipation). A side effect is defined as 'severe' if it may be life-threatening (e.g., agranulocytosis).

c. **Visibility:** A side effect id defined as 'visible' if it is definitely detectable (e.g., rash). This includes detection by the patient or by someone other than the patient. A side effect is defined as 'may be visible' if the detectability is less clear cut. For example, a headache is not exactly visible, per se. However, the patient may be able to convey that he has a headache. In these cases, it is assumed that the patient is responsive or communicative. Also, assessment is based on a physical examination which may include use of a blood pressure cuff, thermometer, stethoscope, weight measurement, and fluid input/output measurement. Finally, a side effect is defined as ' not visible' if it is definitely not visible (e.g., neutropenia), or if it is not detectable by routine physical exam.

d. **Lab tests:** The intent of this indicator is not to establish which lab tests should be ordered for a given drug as baseline or for monitoring. Rather, it is intended to indicate whether or not lab tests are necessary as follow-up for a given drug/side effect pair.

e. **Physician:** The physician should always be contacted regarding severe side effects. In addition, the physician should be contacted whenever lab tests are required.

6 - 3 Maximums and Minimums

Utah Medicaid has implemented the Maximums and Minimums fields with acceptable quantities. Drugs available in certain quantities are covered in that quantity and multiples of those quantities. For example, an injectable product only available as a 2.5 ml. vial will have a minimum of 2.5 and a maximum of a multiple of 2.5. Products such as antibiotics in 75 ml, 100 ml, 150 ml., or 200 ml are covered only in those quantity and multiples of those quantities. Other quantities, such as 35 ml for a 75 ml product, or 430 for the product, are not covered.

6 - 4 Decimal Quantities

Starting July 1, 1998, pharmacies must bill using metric decimal quantities to the second decimal when entering the units dispensed. Use metric decimal quantity field (Field 442-E7). This change affects ophthalmic preparations, otic preparations, inhalers and selected injectable preparations. For example: Vanceril® inhaler (NDC 00085073604) must be expressed as 16.80 units or an even multiple of 16.80 units. (Examples: 2 x 6.80 = 33.60 units; 3 x 16.80 = 50.40 units).

As of July 1, 1998, you may no longer round up the decimal quantity to the next whole number. If the decimal quantity is rounded up to the next whole number, the claim will be rejected.
When the Point of Sale program began in 1994, each pharmacy that signed on agreed to accept Version 3.2 of NCPDP's standardized electronic claims format. As of July 1, the standard will change to require decimal quantities to the second decimal.

6 - 5 Counseling

Effective use of the Point-of-Sale and PRODUR systems is the basis for patient counseling.

Patient counseling is mandated by OBRA 1990, OBRA 1993, and Utah Pharmacy Practice Act. Counseling the client and interfacing with the physician are integral parts of the pharmacy function of dispensing. Audits of pharmacies are performed regularly in conjunction with the Department of Professional Licensing (DOPL).

Counseling is included as part of the dispensing fee, and the pharmacist must instigate dialog by offering to counsel the client. Mail order pharmacies which do not offer counseling up-front are subject to a lesser fee. Providing the package insert is not considered counseling.

6 - 6 Rebate Program

OBRA 1990 mandates that all drug manufacturers whose products were dispensed to Medicaid clients provide a discount or rebate back to the individual states. Medicaid is the single largest user of drugs nationwide and, as such, is entitled to a discount such as hospitals and other organizations receive.

Each quarter of a calendar year, Medicaid produces a list of drugs by National Drug Code (NDC). The list includes the number of units of each NDC which the state has paid to all pharmacies. The list is sent to each manufacturer. The manufacturer applies its rebate criteria, multiplies the number of units by the rebate per unit (RPU) and pays Medicaid that rebate amount.

To ensure accuracy in the drug list, pharmacies shall ensure claims submitted conform with the following reporting requirements:

1. All products must be billed with correct decimals for any fractions dispensed. Here are some examples of correct decimals for fractional quantities: 2.5ml; 15 gram tubes; 12.5 for 1/8 oz. ointments; 15.7ml inhalers.

2. All medications must be billed in accurate quantities, particularly injectable medications. Liquid vials should be billed by ml. For example, a 10 ml. vial equals 10 units, a 20 ml. vial equals 20 units. Dry powder vials are billed as 'each'. Each vial equals quantity one. The diluent used to liquefy a dry powder is billed separately by NDC and units (ml.) of liquid.

   Some items are limited by computer edits to allow only a specified minimum or an even multiple of that minimum, i.e. 3 x 2.5ml.

3. Ensure that your computer entries for quantities are accurate.

   Pharmacies shall make sure that computer 'stutter' does not result in inaccurate quantities, such as 60,000 instead of 60.

4. Only the NDC of the product dispensed is billed. The NDC for the generic brand is billed when a generic brand is dispensed. Do NOT bill Medicaid for a name brand NDC when a generic brand was dispensed. Common billing errors include billing for Darvocet N, Keflex, Mellaril, Stelazine, or Depakene when generics were dispensed.

5. The pharmacist or technician shall write the name of the manufacturer on the prescription when actually transferring a product from a stock container into a vial for a specific patient. To ensure accuracy, Medicaid requires the name of the manufacturer to be written on the prescription by the pharmacist or technician who is actually holding the product dispensed. A manufacturer is permitted under OBRA 90 to request verification of the NDC billed to Medicaid or requesting invoices to substantiate purchases.

   Manufacturers gather data such as names, addresses, reimbursement and specific errors made by pharmacies when dispensing. Manufacturers assume it is not likely that pharmacies repeatedly accept generic reimbursement while billing innovator NDCs. Therefore, when a manufacturer denies the rebate and names pharmacies which billed for name brand NDCs but accepted generic level reimbursement, both the manufacturer and Medicaid will request a copy of the prescription to verify the manufacturer written on the prescription and a copy of the pharmacy purchase invoice. Suitable penalties will be applied when discrepancies exist between the manufacturer identified and the NDC billed.

6 - 7 J-Code Billing

In order to comply with the provisions of the Deficit Reductions Act of 2006, section 6002, billings for medications administered in the physician's office must include the National Drug Code (NDC) from the container from which the medication is obtained, and the number of units administered in addition to the "J" Code normally used. Billings for all drugs administered in the physician's office without the NDC information will be denied for payment beginning with the reporting deadline of January 1, 2007, specified in the DRA for single source drugs.

The following information must be provided on a CMS-1500 Claim Form when billing for office administered drugs:

A. NDC - Box 24D, shaded area
B. Drug Unit Price - Box 24F, shaded area
C. Basis of Measurement Qualifier and Units - Box 24G, shaded area. Use the following qualifiers:

- ME - for milligrams
- ML - for milliliters
- GR - for grams
- UN - for units

Outpatient hospital departments that are billing individually for drugs must also provide the NDC when billing Medicaid on the UB-04 claim form.

When billing a procedure that requires a NDC code (done under contract with a payer), enter the NDC on the line immediately below the REV Code and Procedure Code (Form locator 43), the Units preceded by a qualifier (Form locator 46), and the Unit Price (Form locator 47).

When billing the CMS-1500 or the UB-04 electronically, the information needs to be reported in the following X12 fields (contact your software vendor for specific information):

2410 LIN03= NDC number preceded with N4 (LIN02=N4).
2410 CTP05-1= Units qualifier (GR, ML, ME, UN)
2410 CTP04= Number of units (place the number of units immediately after the units qualifier)
2410 CTP03= Cost or Unit Price

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